K101309

510(K) SUMMARY

Date Revised: July 22, 2010

1.1 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By: Armand Hamid
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OCT 20 2010

1.1	Trade/Proprietary Name	EXELINT Aluminum Hub Blunt Needles
1.2	Common/Usual Name	Blunt Fluid Transfer Needle
1.3	Classification Name	Needle, hypodermic, single lumen
1.4	Classification	Class: II Panel: 80 Product Code: FMI Cite: 21 CFR 880.5470

1.5 Description

The EXELINT Aluminum Hub Blunt Needles are sterile, non-pyrogenic, single use fluid transfer needles consisting of blunt Type 304 stainless steel cannulas staked into aluminum luer lock hubs. The gauge and length of the cannula determines the final gauge and length of the product. The hubs are identical for all of the needles. Each needle is packaged into a Polypropylene tube and sealed with a polypropylene cap. The needles are final packaged into a multi-needle box and ETO sterilized.

1.6 Indication for Use

The product is intended to be used in a variety of medical, pharmaceutical and laboratory procedures to extract fluid or medication from vials or ampoule for transfer or for irrigation.

1.7 Substantial Equivalence

The devices are substantially equivalent to the *MONOJECT® Rigid Pack Blunt Cannula*, cleared as the Monoject Sterile M200 Aluminum Hub Blunt Cannula Device under 510(k) file number K854547.

1.8 Technological Characteristics

The EXELINT Aluminum Hub Blunt Needles are constructed of the same materials (aluminum and Stainless steel), have the same dimension (lengths, gauges), are sterilized with EtO in packaging of the same materials, design and colors, and comply with the same standards as the currently marketed predicate products.

1.9 Performance Data

The devices were tested and found in compliance with the ISO standards for Needles (ISO 7864) and Stainless Steel Tubing (ISO 9626). The packaging was tested for seal strength. These tests demonstrated that the EXELINT Aluminum Hub Blunt Needles are safe and effective and that their performance meets the requirements of their pre-defined acceptance criteria and intended use.

1.10 Conclusion

EXELINT International concludes based on the information presented that the new products lines are substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Armand Hamid
Director
Exelint International Company
5840 W. Centinela Avenue
Los Angeles, California 90045

OCT 20 2010

Re: K101309
Trade/Device Name: EXELINT Aluminum Hub Blunt Needles
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: September 27, 2010
Received: September 30, 2010

Dear Mr. Hamid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 2 0 2010

510(k) Number: K101309

Device Name: EXELINT Aluminum Hub Blunt Needles

Indications for Use: The EXELINT Aluminum Hub Blunt Needles are intended to be used in a variety of medical, pharmaceutical and laboratory procedures to extract fluid or medication from vials or ampoule for transfer or for irrigation.

Prescription Use ✓ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/20/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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